Special 510(k): Device Modification
Turbo-Ject® Peripherally Inserted Central Venous Catheter (PICC)
COOK INCORPORATED
6 June 2011

K111244

JUN 14 2011

510(k) SUMMARY

Submitted By: Mironda Carpenter
Regulatory Affairs Specialist
Cook Incorporated
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402
(812) 339-2235 x 2827
June 6, 2011

Device:

Trade Name: Turbo-Ject® PICC Set

Proposed Classification Name: Percutaneous, Implanted, Long-Term Intravascular Catheter

21 CFR §880.5970, Product Code LJS

Indications for Use:

The Turbo-Ject® PICC is indicated for short- or long-term use for venous pressure monitoring, blood sampling, administration of drugs and fluids, and for use with power injectors for delivery of contrast in CT studies. The Turbo-Ject® PICC is indicated for multiple injections of contrast media through a power injector. The maximum pressure limit setting for power injectors used with the Turbo-Ject® PICC may not exceed 325 psi and the flow rate may not exceed the maximum flow rate indicated.

Catheter Size	Maximum Flow Rate*	Injection Pressure Limit Setting
3.0 Fr Single Lumen	2 mL/sec	325 psi
4.0 Fr Single Lumen	4 mL/sec	325 psi
5.0 Fr Single Lumen	7 mL/sec	325 psi
5.0 Fr Double Lumen	5 mL/sec	325 psi
6.0 Fr Triple Lumen**	7 mL/sec	325 psi

*Flow rates achieved using room temperature Omnipaque 300® contrast and verified using a Medrad Stellant® CT injector system. Omnipaque 300 has a viscosity of 11.8 centipoise at room temperature (20 degrees C). A change in temperature or viscosity of the contrast medium used will result in a change in achievable flow rates.
**Lumen #1 only.
Omnipaque 300® is a registered trademark of GE Healthcare.

Predicate Devices:

Turbo-Ject® Peripherally Inserted Central Venous Catheter (PICC), 510(k) number K072625

Spectrum® Turbo-Ject® Peripherally Inserted Central Venous Catheter (PICC), 510(k) number K100974

Device Description:

The Turbo-Ject® PICC catheters are radiopaque polyurethane peripherally inserted central venous catheters for short- or long-term use, and can be inserted through a Peel-Away® introducer, or over-the-wire. The currently marketed Turbo-Ject® PICCs are available in the following configurations: 4.0 Fr single lumen, 5.0 Fr single lumen, and 5.0 Fr double lumen. The currently marketed Spectrum® Turbo-Ject® PICCs are available in the following antimicrobial agent impregnated configurations: 3.0 Fr single lumen, 4.0 Fr single lumen, 5.0 Fr single lumen, 5.0 Fr double lumen, and 6.0 Fr triple lumen. The proposed devices add two additional non-impregnated configurations, a 3.0 Fr single lumen catheter and a 6.0 Fr triple lumen catheter.

Substantial Equivalence:

The proposed Turbo-Ject® PICC is similar to many devices in commercial distribution indicated for short- or long-term use for venous pressure monitoring, blood sampling, administration of drugs and fluids, and for use with power injectors for delivery of contrast in CT studies. The Turbo-Ject® PICC in 3.0 Fr and 6.0 Fr are within the range of previously cleared Turbo-Ject® PICC devices (cleared under premarket notification 510(k) number K072625) in regards to the intended use, technological characteristics, and material. The Turbo-Ject® PICC in 3.0 Fr and 6.0 Fr are also within the range of previously cleared Spectrum® Turbo-Ject® PICC devices (cleared under premarket notification 510(k) number K100974) in regards to intended use, technological characteristics, and configurations.

The differences between the proposed Turbo-Ject® PICC and the predicate Turbo-Ject® PICC, D.C. # K072625, include French size, length (proposed 3.0 Fr device is shorter), number of lumens (proposed 6.0 Fr device has three lumens), and flow rate. The difference between the proposed Turbo-Ject® PICC and the predicate Spectrum® Turbo-Ject® PICC, D.C. # K100974, is the antimicrobial agent on the predicate device. The proposed devices add two additional non-impregnated configurations, a 3.0 Fr single lumen catheter and a 6.0 Fr triple lumen catheter. The similar technological characteristics of the devices support a determination of substantial equivalence.

Test Data:

The following tests were performed to demonstrate that the Turbo-Ject® PICC meets applicable design and performance requirements and supports a determination of substantial equivalence.

- Static Failure Pressure – Testing shows the pressures reached during proper clinical use (maximum pressure at maximum flow rate) are less than the static burst pressure of the catheter, and should not fracture or rupture the catheter. Predetermined acceptance criteria met.
- Flow Rate – Testing shows the pressure exerted at the maximum flow rate during proper clinical use should not fracture or rupture the catheter. Predetermined acceptance criteria met.
- Tensile Strength – Testing shows the tensile strength during proper clinical use should not fracture or rupture the catheter. In conformance with the applicable sections of BS EN ISO 10555-1:2009, predetermined acceptance criteria were met.
- Biocompatibility – Testing shows the device is biocompatible. In conformance with the applicable sections of BS EN ISO 10993-1:2009, predetermined acceptance criteria were met.

In conclusion, the results of these tests provide reasonable assurance that the device is safe and effective for its intended use and supports a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 14 2011

Ms. Mironda Carpenter
Regulatory Affairs Specialist
Cook, Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, Indiana 47402

Re: K111244
Trade/Device Name: Turbo-Ject® Peripherally Inserted Central Venous Catheter (PICC)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: June 6, 2011
Received: June 7, 2011

Dear Ms. Carpenter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111244

Device Name:

Turbo-Ject® Peripherally Inserted Central Venous Catheter (PICC)

Indications for Use:

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**Lumen #1 only.
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Prescription Use XX OR Over-the-Counter Use____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Acting for Richard Chapman
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111244